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No. 04-623

In The Supreme Court of the United States

ALBERTO R. GONZALES,
ATTORNEY GENERAL, et al.,

Petitioners,

v.

STATE OF OREGON, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF THE STATES OF CALIFORNIA, MISSISSIPPI, MISSOURI, MONTANA, AND THE DISTRICT OF COLUMBIA AS AMICI CURIAE IN SUPPORT OF RESPONDENT STATE OF OREGON

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INTEREST OF AMICI CURIAE

Amici States all regulate the practice of medicine. They are all concerned about the need to balance respect for personal liberty and the interests of their broader societies in addressing sensitive end-of-life issues. Amici states all prohibit physician assisted suicide.[1] Nevertheless, amici support the State of Oregon in this matter because petitioners claim administrative authority to interfere with Oregon's regulation of the practice of medicine. Such a claim must be supported by unmistakable congressional authorization. It is not.

At issue here, is not the question of Congress' authority to regulate the practice of medicine. Rather, the question is whether Congress intended in the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, to regulate the practice of medicine. That is, did Congress intend to delegate to the United States Attorney General authority to supervise state regulation of the practice of medicine by prosecuting duly licensed physicians and denying them the ability to practice their trade – for *lawfully* prescribing Schedule II drugs in medical procedures that the Attorney General deems to be "illegitimate."

Regulation of the practice of medicine has long been regarded as the responsibility of the individual sovereign States. See, *e.g, Linder v. United States*, 268 U.S. 5, 18 (1924) ("Obviously, direct control of medical practice in the states is beyond the power of the federal government."). Amici, therefore, join Oregon in contending that the United States Attorney General's assertion of the prerogative to evaluate a State's legislative policy concerning

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[1] See, *e.g.*, Cal. Pen. Code § 401 (2005); Mo. Rev. Stat. § 565.023 (2000); Mont. Code Ann. § 45-5-105 (2003); Miss. Code Ann. § 97-3-49.

medical practice and the physician-patient relationship must be grounded in "a clear indication that Congress intended that result." *Solid Waste Agency of Northern Cook County v. United States Corps of Engineers*, 531 U.S. 159, 172 (2001). Amici further contend that such a sweeping grant of federal power is not included in the Controlled Substances Act.

SUMMARY OF ARGUMENT

Physicians have long understood that prescribing Schedule II narcotics in violation of state law may subject them to federal prosecution and loss of prescribing privileges under the Controlled Substances Act. But, for the first time in the 30-year history of that Act, duly licensed physicians in Oregon face federal prosecution and administrative penalties because they prescribed a Schedule II narcotic *in full compliance* with state law. The sole offense of these doctors will be participation in a medical procedure that, though sanctioned under Oregon state law, is not similarly sanctioned by other States or by professional organizations and is, therefore, deemed to be "illegitimate" by the Attorney General of the United States.

This is a dramatic alteration of the traditional federal-state allocation of legislative responsibility. States have generally enjoyed "broad powers" in matters concerning the practice of medicine for protection of the health and welfare of their citizens. *Barsky v. Board of Regents of the State University of New York,* 347 U.S. 442, 449 (1954). And a value consensus among the States regarding medical matters is not a measure of the validity of any one State's legislative policy Cf., *Franchise Tax Bd. of California v. Hyatt*, 538 U.S. 488 (2003) (Full Faith and Credit

Clause does not compel a State to substitute statutes of other States for its own statutes dealing with a subject matter concerning which it is competent to legislate). Indeed, experimentation by States in the regulation of social matters has long been regarded as a bedrock of Federalism. See *New State Ice Co. v. Liebmann,* 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (States as "laboratories" of democracy.) "The essence of federalism is that states must be free to develop a variety of solutions to problems and not be forced into a common, uniform mold." *Addington v. Texas*, 441 U.S. 418, 431 (1979).

An intrusion into the traditional purview of state legislative control by an administrative agency such as is effected by the Attorney General's "directive" here must be grounded in a clear expression of congressional intent. However, nothing in the Controlled Substances Act delegates to the Attorney General authority to interfere with State regulation of the practice of medicine.

ARGUMENT

ADMINISTRATIVE INTERFERENCE WITH STATE AUTHORIZATION OF A MEDICAL PROCEDURE MUST BE GROUNDED IN CONGRESS' CLEARLY EXPRESSED INTENT TO SUPERVISE STATE REGULATION OF MEDICAL PRACTICE; NO SUCH EXPRESSION IS EVIDENT IN THE CSA.

A. Regulation of Medical Practice, Including End-of-life Issues, Is Traditionally Left to the Sovereign and Independent Policy Judgment of Each State.

In November 1994, by ballot initiative, a "basic instrument of democratic government," *Eastlake v. Forest*

City Enterprises, Inc., 526 U.S. 668, 679 (1966), Oregon voters enacted the Death With Dignity Act, Or. Rev. Stat. §§ 127.800-127.995 (2003). The citizens of Oregon subsequently reaffirmed the measure when, in November 1997, an initiative seeking its repeal was defeated.

Traditionally, States "have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons," *Medtronic Inc. v. Lohr*, 518 U.S. 470, 475 (1996), quoting *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985). This Court has characterized as "elemental" the proposition that States have "broad power" to establish within their borders standards of conduct relative to health. *Barsky v. Board of Regents of the State University of New York*, 347 U.S. at 449; see also, *Linder v. United States*, 268 U.S. at 18.

The scope of the States' inherent authority over medical practice cannot be confined to ascertaining whether accepted medical procedures have been competently performed. It reasonably must include the authority to decide what medical procedures are acceptable to perform in the first instance and, within the Constitution's limits, to specify the conditions under which medical procedures may be lawfully performed. Cf., *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846 (1992) (confirming State's interest in regulating abortion availability after viability).

Seldom have States been of one mind, as a matter of legislative policy, about the "legitimacy" of every new medical procedure that develops. Most recently, the Court

noted state variation in authorizing the use of marijuana in medical treatment. *Gonzalez v. Raich*, 545 U.S. ___, 125 S.Ct. 2195, 2198-99 (2005) (noting that at least ten States authorize marijuana for medical purposes). And today, States wrestle with difficult ethical issues surrounding human stem cell research. Eight States, for example, have enacted explicit laws to ban reproductive cloning; four of those also ban therapeutic cloning; and one State only prohibits the use of state funding in reproductive cloning Andrews, *Legislators as Lobbyists: Proposed State Regulation of Embryonic Stem Cell Research, Therapeutic Cloning and Reproductive Cloning*, Appendix E to *Monitoring Stem Cell Research*, President's Council on Bioethics (January 2004).[2] Some of the States that ban reproductive cloning actively encourage therapeutic cloning.[3]

State policy disagreement over some medical procedures has been a reality for much of our history. Birth control and abortion are obvious examples of medical procedures that some States came to accept as a matter of state policy while others did not. At the time of this Court's decision in *Griswold v. Connecticut*, 381 U.S. 479 (1965), for example, 30 States had laws relating to birth control. See Brief for Appellee in *Griswold v. Connecticut*, O.T. 1964, No. 496, p. 7. In 1960, thirteen years before *Roe v. Wade*, 410 U.S. 113 (1973), every state criminal code included provisions forbidding abortion under most circumstances. Graber, *The Ghost of Abortion Past: Pre-Roe Abortion Law in Action*, 1 Va. J. Soc. Pol'y & L. 309, 360

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[2] Available at: http://www.bioethics.gov/reports/stemcell/appendix_e.html.

[3] See, *e.g.*, Cal. Health & Saf. Code, §§ 24185, 125300 (2005); N.J. Stat. Ann. § 26:2Z-2 (West Supp. 2004).

(1994). But by 1973, some state legislatures had removed those restrictions,[4] while in other States therapeutic abortion remained a proscribed medical procedure as a matter of local legislative choice.

Sex-reassignment surgery is another example of a medical procedure whose "legitimacy" may be questioned by some but which is nevertheless permitted in States today. According to one commentator, "[t]he national and international medical community overwhelmingly endorses sex-reassignment surgery and hormones as the only known medical treatment for transsexuals." Hong, *Categorical Exclusions: Exploring Legal Responses to Health Care Discrimination Against Transsexuals*, 11 Colum. J. Gender & L. 88, 91 & n. 18 (2002). But at common law, castration amounted to felonious mayhem, 4 William Blackstone, Commentaries *206, and consent to mayhem was no defense, see Twardy, *Medicolegal Aspects of Transsexualism*, 26 Medical Trial Technique Q. 249, 297-310 (Winter 1980). Indeed, in the opinion of some, the common law criminalization of castration precluded even voluntary vasectomy. See, *e.g.*, 15 Ops. Cal. Atty. Gen. 100, 103 (1950), *citing* Miller & Dean, *Liability of Physicians for Sterilization Operations,* XVI ABA Journal 158, 159 (1930); but see *Jessin v. Shasta County*, 79 Cal.Rptr. 359 (Cal. App. 1969); *Christensen v. Thornby,* 255 N.W. 620, 622 (Minn. 1934) ("[A vasectomy] does not render the patient impotent or unable 'to fight for the king,' as was

[4] Prior to *Roe*, statutes permitting non-therapeutic abortions had been enacted in Hawaii (1971), New York (1971), Alaska (1970) and Washington (1971). *Id.*

the case in mayhem or maiming").[5] Today, no state expressly prohibits male-female sex-reassignment surgery, though States are not always in agreement about the therapeutic value of the medical procedure. Compare, *e.g.*, *Rush v. Johnson*, 565 F.Supp. 856 (D.C. Ga. 1983); (State's determinations that "transsexual" surgery was not generally accepted by the professional medical community as a proven and effective treatment and that there was no authority of evidence that the surgery is safe and effective were reasonable) and *G.B. v. Lackner*, 145 Cal.Rptr. 555 (Cal. App. 1978) (proposed surgery to reconstruct genitalia as treatment for gender identity dysphoria could not be arbitrarily classified as "cosmetic" and thus claimant was entitled to Medi-Cal assistance).[6]

The extremely important medical procedure of organ transplantation could never have developed were it not for

[5] One comment reports that as of 1965, three States had enacted statutes declaring voluntary sterilization (male or female) to be a crime "unless performed under the provisions of the compulsory eugenic statutes or by a private physician where there is a 'medical necessity'" Champlin & Winslow, *Elective Sterilization*, U. Pa. L. Rev. 415, 427 (1965). And one of those statutes imposed criminal penalties on the person submitting to the procedure. *Id.*; Conn. Gen. Stat. Rev. § 53-33 (1958).

[6] Still today, States must wrestle with the legal/ethical question whether sex-change operations may be performed *involuntarily* on intersexed children who are too young to consent. See, *e.g.*, Beh & Diamond, *An Emerging Ethical and Medical Dilemma: Should Physicians Perform Sex Assignment Surgery on Infants With Ambiguous Genitalia?*, 7 Mich. J. Gender & L. 1 (2000). And, as the complexity of the human condition is slowly being recognized, States will be called upon to consider the ethical and legal parameters appropriate to medical disfigurement procedures at what are certainly the "outer edges" of today's acceptability. See, *e.g.*, Bridy, *Confounding Extremities: Surgery at the Medico-Ethical Limits of Self-Modification*, 32 J.L. Med. & Ethics 148 (2004).

the willingness of States to depart from common law proscriptions in deference to changes in public sentiment. At common law, no one had power to convey his body parts after death, because the common law recognized no property right in one's body See 22A Am. Jur. 2d Dead Bodies, § 3 (1988). And anatomical dissection at common law was so reprehensible a notion as to have been reserved as an additional post-mortem punishment to exact against the corpse of an executed murderer. See 4 William Blackstone, Commentaries *202; Keller, *The Bed of Life: a Discussion of Organ Donation, Its Legal And Scientific History, And a Recommended "Opt-out" Solution to Organ Scarcity*, 32 Stetson L. Rev. 855, 863-64 (Summer 2003). States initially differed on their treatment of body and organ donation, but in the 1960s, the National Conference of Commissioners on Uniform State Laws began the process of formulating a model organ donation act. By 1972, some version of the Uniform Anatomical Gift Act had been adopted in every State and the District of Columbia. See Cate, *Human Organ Transplantation: The Role of Law*, 20 J. Corp. L. 69, 71 & n. 24 (1995).

Advances in medicine and advances in understanding of the human physical and psychological condition increasingly present issues of great sensitivity and controversy. But, "[t]he science of government ... is the science of experiment," *Anderson v. Dunn*, 19 U.S. (6 Wheat.) 204, 226 (1821), and the Court has often acknowledged the States' important role as "laboratories" of democracy. *New State Ice Co. v. Liebmann* 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of

the country.") The Constitution does not compel policy consensus among the States. Cf. *Franchise Tax Bd. of California v. Hyatt*, 538 U.S. 488 (2003) (Full Faith and Credit Clause does not compel a State to substitute statutes of other States for its own statutes dealing with a subject matter concerning which it is competent to legislate).[7]

State experimentation in social policy has been the source of many important innovations, such as the right of women to vote, the advent of unemployment insurance and minimum-wage laws, and environmental protection. See *F.E.R.C. v. Mississippi*, 456 U.S. 742, 788-89 (1982) (O'Connor, J., dissenting). The Court recognized nearly a decade ago that the States were "engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues." *Washington v. Glucksburg*, 521 U.S. 702, 719 (1997). Indeed, the Court was concerned that, by extending constitutional protection to an asserted right to end one's life, it would, "to a great extent, place the matter outside the arena of public debate and legislative action." *Id.* at 720.

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[7] Nor have the States surrendered their policy-making responsibility to professional associations. At best, the views and opinions of professional associations amount to a kind of "soft law," Campbell & Glass, *The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research*, 46 McGill L. J. 473 (2001), guiding the conduct of members but having no constitutional status elevating those views over the legislative choices of the States within which the members practice. Indeed, state legislatures may determine that public necessity and circumstance warrant a quality of medical practice different from that which is currently accepted within the profession. As one court observed, "[r]espect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves." *Canterbury v. Spence*, 464 F.2d 772, 784 (C.A.D.C. 1972) (re sufficiency of surgeon's disclosure).

Federalism's wisdom of deferring to the States' inventiveness for solving pressing issues of public health and welfare has no less force because one State's experiment challenges conventional norms. Reflection on the traditions from which States *break* is as important as reflection on the traditions to which they *adhere* in discerning an appropriate constitutional balance between respect for individual rights and the demands of organized society. See *Poe v. Ullman*, 367 U.S. 497, 542 (1961) (Harlan, J., dissenting from dismissal on jurisdictional grounds), quoted in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 849 (1992); cf., *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528, 545-46 (1985) (The "essence of our federal system is that within the realm of authority left open to them under the Constitution, the States must be equally free to engage in any activity that their citizens choose for the common weal, no matter how unorthodox or unnecessary anyone else . . . deems state involvement to be."). If "federalism's capacity for institutional innovation," Tribe, *American Constitutional Law* (3d ed.) 910, justifies deference to state experimentation with remedies for chronic cement shortages, see *Reeves v. Stake*, 447 U.S. 429, 441 (1980), it surely justifies deference to state experimentation in resolution of "the difficult, indeed agonizing, questions that are presented by the constantly increasing power of science to keep the human body alive for longer than any reasonable person would want to inhabit it." *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 292 (1990) (Scalia, J., concurring).

B. Congress Did Not Intend in the Controlled Substances Act to Delegate to the Attorney General Authority to Supervise State Regulation of Medical Practice.

This case does not present the question whether Congress could, under the Commerce Clause, preempt the States in regulating physician treatment of end-of-life matters, though the presumption would certainly be against such preemption. *Medtronic, Inc.*, 518 U.S. at 485. In any event, petitioners here do not squarely argue that Congress intended in the CSA to preempt state regulation of end-of-life medical decisions.

Rather, petitioners rely on the phrase "legitimate medical purpose," which appears in an administrative regulation implementing the CSA, 21 C.F.R. 1306.04. Certainly, that phrase gives the Attorney General power to evaluate the veracity of a physician's asserted justification for prescribing a Schedule II drug. But petitioners argue that the phrase must also be understood to authorize the Attorney General to evaluate the merits of a State's legislative policy in authorizing the prescription under state law in the first instance.

Inasmuch as petitioners claim delegation of the power to preemptively interfere with Oregon's choice to authorize Oregon physicians to perform a medical procedure exclusively within that State, petitioners "invoke the outer limits of Congress' power" and must, therefore, demonstrate "a clear indication that Congress intended that result." *Solid Waste Agency of Northern Cook County v. United States Corps of Engineers*, 531 U.S. 159, 172 (2001); see also *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) ("[I]f Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its

intention to do so unmistakably clear in the language of the statute"); *Alaska Department of Environmental Conservation v. Environmental Protection Agency*, 540 U.S. 461, 513 (2004) (Kennedy, J., concurring) ("[i]f, by some course of reasoning, state[s] . . . must live with the insult that their judgments can be revised by a federal agency, the Court should at least insist upon a clear instruction from Congress.")[8] Whether Congress has the power to impose on a State its view of the "legitimacy" of a medical procedure is not presented here.[9] Rather, the question here

[8] Petitioners dismiss *Solid Waste Agency* as irrelevant. Br. for Pet. at 41 n. 16. But petitioners would have the Court read *Solid Waste Agency* at such a high level of abstraction as to render it meaningless to limit exercise of administrative authority. In this case, the United States Attorney General does not merely invoke congressional power to regulate the distribution of controlled substances as a matter of interstate commerce. Rather, the Attorney General invokes an asserted congressional power to determine – *for the States* – the "legitimacy" as a medical procedure of a use to which a Schedule II drug may lawfully be put under state law. Such a power, touching as it does on an area of traditional state governance, is indeed at the "outer limits" of congressional authority. Cf., *Hillsborough County Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985) (presumption against an intent by Congress in the FDA to preempt local regulation for the protection of blood plasma donors); see also, *DeBuono v. NYSA-ILA Medical and Clinical Services Fund*, 520 U.S. 806, 807 (1997) (no ERISA preemption of state health facility assessment because the assessment "clearly operates in a field that has been traditionally occupied by the States: the regulation of health and safety matters.").

[9] This Court has not yet squarely addressed the question of Congress' power to preempt a State's legislative determination that marijuana has a legitimate medical purpose. See *Gonzalez v. Raich*, 125 S.Ct. at 2204-05 (2005) ("[R]espondents' challenge is actually quite limited; they argue that the CSA's categorical prohibition of the manufacture and possession of marijuana as applied to the intrastate manufacture and possession of marijuana for medical purposes pursuant to California law exceeds Congress' authority under the Commerce Clause."); see also *id.* at 2231 n. 3 (Thomas, J., dissenting); *Raich* held only that, *given* Congress' determination that marijuana has

(Continued on following page)

is whether in the CSA can be found a delegation to the Attorney General of authority preemptively to interfere with a State's administration of its medical practice laws, based on an evaluation of the authorized practice's "legitimacy" – especially when "legitimacy" is not measured against a constitutional standard, but by the approbation of other States and professional medical organizations.

The "main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzalez v. Raich*, 545 U.S. ___ (2005). The CSA was "designed to deal in comprehensive fashion with the growing menace of drug abuse in the United States[.]" *United States v. Moore*, 423 U.S. 122, 141 (1975).

This is not to suggest, of course, that the Attorney General lacks rule making authority under the CSA. But the Attorney General's use of his rule making authority in this instance expands the role of his office into a sort of "junior-varsity Congress," *Mistretta v. United States* 488 U.S. 361, 472, 109 S.Ct. 647, 683 (1989) (Scalia, J., dissenting), substituting a federal agency's notions of medical propriety for the informal legislative policy of the States.

no accepted medical use in treatment – a proposition with which the States were presumably in agreement at the time of enactment – Congress may lawfully proscribe even wholly intrastate cultivation and use of marijuana, notwithstanding that the cultivation and use may be lawful under state law.

Certainly, the legislative history of the CSA suggests a congressional intent to regulate the abuse of prescription privileges to furnish Schedule II drugs in a manner *inconsistent* with accepted medical practice in a State. See 28 U.S.C. §§ 823(f) & 823(a)(4). But nothing in the legislative history of the Act suggests Congress' intention to correct State authorization of permissible uses of Schedule II narcotics.

This "hands-off" policy in respect to regulation of the practice of medicine is consistent with the historic understanding of Congress' intent under the Food, Drug and Cosmetic Act, Pub.L. No. 75-717, 52 Stat. 1040 (1938), codified as amended 21 U.S.C. § 301 *et seq.* (1994). Under long-standing practice, physicians may use legally marketed drugs in any way that they believe, in their professional judgment, will best serve their patients – a prerogative that is repeatedly recognized by the courts and the FDA itself. See Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions,* 53 Food & Drug L.J. 71, 76-77 (1998), cited in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001). Moreover, several state statutes recognize off-label uses in varying contexts. Beck & Azari, *supra*, at 76 n. 56. Nothing in the CSA suggests Congress' intent to change this paradigm of deferring to state regulation of professional prescription practices. Indeed, Congress expressly stated its intention not to preempt state laws that are otherwise within the authority of a State to enact. 21 U.S.C. § 903.

It is evident that former Attorney General Janet Reno saw nothing in the Act or its legislative history to persuade her in 1998 of Congress' intent to enter this area. To the contrary, she noted in a letter to the Chairman of the

House Judiciary Committee that the CSA was not "intended to displace the states as the primary regulators of the medical profession or to override a state's determination as to what constitutes legitimate medical practice." See Pet. App. 7a. The CSA has not been amended since 1998 to suggest that Attorney General Reno was wrong.[10]

Certainly, Congress can state legislative policies under its Commerce Clause powers. And Congress has nullified state legislative choices in furtherance of its powers under the Fourteenth and Fifteenth Amendments. But Amici are unaware of any context wherein it was shown that Congress intended to delegate *to an administrative agency* the power to nullify a state legislative policy, in an area of traditional state regulation, applying a standard of "legitimacy" – measured, not by the Constitution or by reference to conflicting federal enactment, but rather by the policy's acceptance by other States and professional organizations. Merely to state the proposition is to demonstrate its anomaly.

Even if it be assumed that Congress would have the power to make such a delegation of supervisory authority, the delegation must necessarily be unmistakable. And no grant of such authority is evident in the CSA.

[10] In 1998 and 1999, Congress refused passage of a measure to amend the CSA to authorize the United States Attorney General to revoke the registration of practitioners who "intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual." H.R. 4006, 105th Cong. (1998) ("Lethal Drug Abuse Prevention Act of 1998").

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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